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EXAMINER	
ANDERSON, DENISE R	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/579,449	KURODA ET AL.	
	Examiner	Art Unit	
	Denise R. Anderson	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-9 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,6-9 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *26 June 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claim 1 was amended to remove indefiniteness caused by the use of a trademark. The previous 112 rejections of claims 1, 2, and 6-9 are withdrawn.

3. Claims 1, 2, 6-9, and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is shown below, with the indefinite phrase in bold-faced type.

> *Claim 1. (Currently Amended) A hollow fiber membrane for blood purification obtained by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone, and dimethyl acetamide, through an air gap* ***whose solvent gas concentration is 470 ppm or more and 1,000 or less and whose relative humidity is 70% to 95%*** *for 0.4 seconds or more,*
>
> *the hollow fiber membrane having an integrally continuous structure from the inner membrane surface to the outer membrane surface and comprising a hydrophobic polymer and a hydrophilic polymer, and an albumin sieving coefficient of 0.6% or less in a filtrate test using bovine serum, and*
>
> *exhibiting a zeta potential on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin*

on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber, and using a 0.001 mol/1 potassium chloride aqueous solution as an electrolyte solution.

In ¶ 81-82, the Specification discloses, "[I]n the case in which a solvent gas is introduced into the air gap, the structural shrinkage reduces. . . . An optimal solvent gas concentration in the air gap is 150 ppm or more and 1,000 ppm or less." The solvent gas is not further discussed or defined in the Specification. As such, it is unclear how the solvent gas induces a patentable difference to the membrane being claimed. This causes the limitation in bold-faced type to be indefinite.

4. In the patentability analysis below, the examiner will interpret the solvent gas to be water vapor. This is in line with ¶ 80 of the Specification which discloses a method for reducing structural shrinkage of the hollow fiber membrane during manufacture by running the coagulation (water) bath temperature between 80^{O}C 100^{O}C below the air gap. Table 1 shows water vapor concentration in ppm at 70% and 95% relative humidity when temperatures range between 60^{O}C and 95^{O}C and the pressure is atmospheric. Humidity Calculator, http://www.humidity-calculator.com/index.php, accessed on Oct. 17, 2009. As can be seen, water vapor (solvent gas) concentration falls within the 470 to 1000 ppm range recited by the indefinite limitation.

Table 1: Water vapor concentration at atmospheric pressure and relative humidity of 70%, 95%, and 100%.

Temp. ^{O}C	*Ppm, 70% RH*	*ppm, 95% RH*	*ppm, 100% RH*
60	652	931	980
65	629	898	946
70	604	863	908
75	577	824	867
80	546	781	822
85	513	733	772
90	476	681	716
95	436	623	655

Claim Rejections - 35 USC § 103

5. Claim 1, 2, 6, 7, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO02087735 A1, Nov. 7, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited).

6. Claims 8, 9, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO02087735 A1, Nov. 7, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to claims 1, 2, 6, and 7 above – in further view of Carlsen et al. (U.S. Patent No. Re. 36,914, Oct. 17, 2000) for the specifics of the recited blood purification apparatus.

7. Claims 6 and 23 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO02087735 A1, Nov. 7, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to claim 1 above, in further view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002) to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

8. Claim 9 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO02087735 A1, Nov. 7, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited), in view of Carlsen et al. (U.S. Patent No. Re. 36,914, Oct. 17, 2000) for the specifics of the recited blood purification apparatus, as applied to claim 8 above – in further view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002) to teach the phosphorus clearance calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

9. Claim 25 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (WO02087735 A1, Nov. 7, 2002 – the original was in Japanese, so the English version, US 2004/0167237 A1, will be cited) as applied to claim 6 above, in view of Carlsen et al. (U.S. Patent No. Re. 36,914, Oct. 17, 2000) for the specifics of the recited blood purification apparatus – in further view of Kozawa et al. (US Patent No. 6,355,730 B1, Mar. 12, 2002) to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

10. Kim et al. discloses a membrane that is "usable in blood dialysis, plasma separation, etc." Kim et al., Abstract, lines 1-6. Kim et al. further teaches a hollow fiber membrane spun from a solution of aromatic polysulfone, polyvinyl pyrrolidone, and N-methyl-2-pyrrolidone – and the measured zeta potential of the hollow fiber is -1 at pH 7.4, using a 0.001 mol/l potassium chloride solution. Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; ¶ 159. Kozawa et al. discloses hollow fiber membranes formed from polysulfone-based resins and polyvinyl pyrrolidone for use in dialysis. Kozawa et al., Abstract, lines 1-8; col. 2, lines 48-52.

11. Independent claim 1 and dependent claim 7 appear below in italics with the prior art and examiner's comments in normal font.

> *Claim 1. (Currently Amended) A hollow fiber membrane* (Kim et al., ¶ 195, lines 17-18) *for blood purification* (Kim et al., Abstract, lines 1-6) *obtained by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone,* (Kim et al., Comparative Example 1 at ¶ 195 and in Table 1; Kozawa et al., Abstract, lines 1-8, col. 2, lines 48-52) *and dimethyl acetamide, through an air gap whose solvent gas*

concentration is 470 ppm or more and 1,000 or less and whose relative humidity is 70% to 95% for 0.4 seconds or more (Kim et al., ¶ 195, lines 9-13 when Kim et al. teaches, "The extruded hollow fiber was caused to run through a hood saturated with water vapor at an average temperature of 40^{O}C, immersed in water at 55^{O}C in a bath installed 600 mm below the spinneret, and wound around a bobbin at a rate of 50 m/min." As was discussed in the 112 rejection above, the solvent gas is interpreted to be water vapor), *the hollow fiber membrane having an integrally continuous structure* (Kim et al., ¶ 195, line 1, the hollow fiber membrane was spun from a "homogeneous spinning solution" indicating an integrally continuous structure) *from the inner membrane surface to the outer membrane surface and comprising a hydrophobic polymer* (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "aromatic polysulfone" which is a hydrophobic polymer) *and a hydrophilic polymer* (Kim et al., ¶ 195, lines 1-5, the hollow fiber membrane was spun from "polyvinyl pyrrolidone" which is a hydrophilic polymer), *and an albumin sieving coefficient of 0.6% or less in a filtrate test using bovine serum* (Kim et al., Table 1, Comparative Example 1 and Example 1; using calf serum as stated in ¶ 169), *and exhibiting a zeta potential* (Kim et al., Comparative Example 1 at ¶ 195 and in Table 1 where the measured zeta potential was -1 at a pH of 7.4; ¶ 158 where the zeta potential measurement was described and included using a 0.001 mole/l potassium chloride solution) *on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only*

the inside of the hollow fiber, and using a 0.001 mol/1 potassium chloride aqueous solution as an electrolyte solution.

Claim 7. (Previously Presented) The hollow fiber membrane for blood purification according to claim 1, further comprising: a thickness of a dense layer between 1 and 5 μm.

12. Kim et al. discloses the claimed invention except for the humidity in the air gap being saturated, instead of the recited 70% to 95%. Both Kim et al. (¶ 195, lines 9-13) and applicant run the hollow fiber from the spinneret through an air gap and then promptly introduce the hollow fiber into a water bath. In applicant's words the water bath is described as "a coagulation bath containing water as a main component installed below the spinneret." Specification, ¶ 76, lines 12-14. Given both processes use water baths, it would have been obvious to one of ordinary skill in the art to make the Kim et al. hollow fiber with 95% humidity in the air gap instead of 100% humidity since this is the simple substitution of one known element (100 % humidity) for another (95% humidity) to obtain predictable results (the hollow fiber is plunged into a water bath with high humidity at the water bath's interface and the hollow fiber is cooled through the water bath and wound around a bobbin).

13. Regarding the "solvent gas" limitation, this was discussed above in the 112 rejection. As stated there, Kim et al. discloses a solvent gas of water vapor in the air gap which meets the recited limitation of "an air gap whose solvent gas concentration is 470 ppm or more and 1,000 or less and whose relative humidity is 70% to 95%."

14. Kim et al. discloses the claimed invention and teaches the recited "albumin sieving coefficient of 0.6% or less in a filtrate test using bovine serum." Kim et al., Table 1,

Comparative Example 1 and Example 1, using calf serum as stated in ¶ 169. The two Kim et al. examples teach an albumin sieving coefficient of 0.004% to 0.011% as the polyvinyl pyrrolidone content in the spinning solution ranges from 0 to 7 parts, respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the polyvinyl pyrrolidone content in the spinning solution to achieve the recited albumin sieving coefficient of 0.6% or less, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

15. Regarding claim 7, Kim et al. also teaches a dense layer thickness of 1 to 20 μm and this includes applicant's recited range of 1 to 5 μm in claim 7. Kim et al., ¶ 57, lines 5-7.

16. In summary, Kim et al. discloses or suggests all limitations recited in claims 1 and 7.

17. Claims 2 and 6 appear below in italics with the prior art and examiner's comments in normal font.

Claim 2. (Currently Amended) The follow fiber membrane for blood purification according to Claim 1, further exhibiting:

(a) a polyvinyl pyrrolidone sieving coefficient of 45% or more in a filtration test using a polyvinyl pyrrolidone aqueous solution with a weight average molecular weight of 40,000 (Kim et al., ¶ 19, lines 7-13; ¶ 6, lines 4-13),

(b) a protein adsorption amount of 65 mg/m^2 or less (Kim et al., Table 1, Comparative Example 1),

(c) a breaking strength of 60 kg/cm^2 or more, and

(d) a breaking elongation of 60% or more.

Claim 6. (Previously Presented) The hollow fiber membrane for blood purification according to Claim 1, wherein an overall mass transfer coefficient of phosphorous is 0.040 cm/min or greater.

18. Kim et al., in Table 1, Comparative Example 1, discloses a protein adsorption amount of 4.2 mg/m^2 – which is 65 mg/m^2 or less, as recited. Kim et al. also teaches that a "first object of the present invention" is to provide a hollow fiber membrane "that can separate a human serum albumin with a molecular weight of about 67,000 from proteins with a molecular weight in the range of 30,000-40,000." Kim et al., ¶ 19, lines 7-13; ¶ 6, lines 4-13. Thus, the Kim et al. hollow fiber membranes will remove more than 45% of a polyvinyl pyrrolidone with a weight average molecular weight of 40,000.

19. Kim fails to disclose the property limitations recited in claim 2, subparagraphs (c) and (d) which are the breaking strength and breaking elongation of the membrane. Kim also fails to disclose applicant's calculated – not measured – mass transfer coefficient shown in the Specification, ¶ 49 that applicant recites must be "0.040 cm/min or greater" in claim 6. However, a membrane's properties are determined by its composition, and the polymer membrane of the reference has the same composition as the polymer membrane described by instant claim 1. For these reasons, the cited properties are presumed to be inherent to the membrane of the reference. See MPEP 2112.

20. In summary, Kim et al. discloses or suggests all limitations recited in claims 2 and 6.

21. Regarding claims 8 and 9, Kim et al. discloses the claimed invention except for the specifics of the recited blood purification apparatus. Carlsen et al. discloses a "dialysate filter" (applicant's blood purification apparatus) that has "an asymmetric microporous, hollow fiber membrane." Carlsen et al., Title, Figures 1 and 2. Claims 8 and 9 are shown below in italics with the examiner's comments in normal font.

> *Claim 8. (Previously Presented) A blood purification apparatus* (Carlsen et al., Fig. 2) *comprising the hollow fiber membrane according to claim 1, installed in a cylindrical container having two nozzles* (Carlsen et al., Fig. 2, cylindrical container with inlet port and outlet port) *for flowing a dialysate, the cylindrical container having both ends fabricated with a potting material* (Carlsen et al., col. 11, lines 30-32) *for separating the hollow inside of the membrane from the outside by a membrane wall and the cylindrical container further having a header cap for flowing blood fitted on both ends* (Carlsen et al., Fig. 2, cylindrical container with header cap at both ends).
>
> *Claim 9. (Previously Presented) The blood purification apparatus according to claim 8, wherein the hollow fiber membrane has a phosphorus clearance of at least 180 ml/min per a membrane area of 1.5* m^2.

22. Regarding claim 8 – In Fig. 2, Carlsen et al. discloses a cylindrical container with two nozzles (labeled "inlet port" and "outlet port") for flow dialysate. Carlsen et al. further teaches a potting material to separate the hollow inside of the membrane from the outside of the membrane. Carlsen et al., col. 11, lines 30-32. Finally, in Fig. 2, Carlsen et al. discloses a header cap at both ends of the apparatus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have installed the Kim et al. hollow fiber

membranes into a blood purification apparatus, as taught by Carlsen et al., since Kim et al. states in the Abstract, lines 1-5 that the Kim et al. hollow fiber membranes are "usable in blood dialysis" and Carlsen et al states in the Title that the Carlsen et al. apparatus is a "dialysate filter" incorporating "hollow fiber membranes."

23. Regarding claim 9, Kim et al., in view of Carlsen et al., discloses the claimed invention except for explicitly stating that the phosphorus clearance is 180 ml/min for a 1.5 m^2 membrane area. Because the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant and structure governs phosphorous clearance, the Kim et al. hollow fiber membrane in the Carlsen apparatus would exhibit the phosphorous clearance of 180 ml/min for a 1.5 m^2 membrane area. Thus, Kim et al., in view of Carlsen et al., discloses or suggests all claim 9 limitations.

24. In summary, Kim et al., in view of Carlsen et al. for the specifics of the blood purification apparatus, discloses or suggests all limitations recited in claims 8 and 9.

25. There is a second argument regarding the recited calculation of overall mass transfer coefficient [claim 6] and phosphorus clearance [claim 9]. Kozawa et al. discloses a method to calculate both phosphorus clearance [claim 9] and overall mass transfer coefficients [claim 6] in the context of, "Membrane materials for removing uremic toxins from a hydrophobic polymer such as polysulfone and two polyvinyl pyrrolidones, hydrophilic polymers of different molecular weights, that is 10-50 wt. % of a low molecular weight component (molecular weight < 100,000) and 90-50 wt. % of a high molecular weight component (molecular weight $\geq$ 100,000). The membranes are permselective useful in dialysis." Kozawa et al., Abstract, lines 1-8.

Unfortunately, the Kozawa et al. phosphorus clearance calculation was different from that of applicant and there is not enough data to put the two calculations on the same basis. Kozawa et al., col. 7, lines 49-66. Applicant's Specification, ¶¶ 49-55. Similarly, since the overall mass transfer calculation is based on the clearance calculation, there is not enough data to put applicant's calculation on the same basis with that of Kozawa et al.

26. Because calculations of phosphorus clearance and overall mass transfer coefficients are different between applicant and Kozawa et al., the examiner will continue to make the argument that the structure of the Kim et al. hollow fiber membrane is the same as that recited by applicant. Since the structure governs both phosphorous clearance and the overall mass transfer coefficient, the Kim et al. hollow fiber membrane would exhibit the phosphorous clearance or overall mass transfer coefficient recited in the claim. The argument will be supplemented with the teaching from Kozawa et al. that calculating phosphorus clearance and overall mass transfer coefficients are known in the membrane art in the context of polysulfone / polyvinylpyrrolidone hollow fibers used in blood purification.

27. In summary, Kim et al., in view of Kozawa et al. to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification, discloses or suggests all claim 6 limitations.

28. Kim et al., in view of Carlsen et al. for the specifics of the blood purification apparatus, in further view of Kozawa et al. to teach the phosphorus clearance calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification, discloses or suggests all claim 9 limitations.

29. New claims 21-26 recite the same limitations of the previous claims but mix and match the limitations differently. As such, the claims are rejected as follows.

Claim 21. (New) The hollow fiber membrane for blood purification according to Claim 2, wherein an overall mass transfer coefficient of phosphorous is 0.040 cm/min or greater.

Claim 21 recites the same limitation as claim 6. Claim 21 depends on claim 2 while claim 6 depends on claim 1. Claims 1, 2, and 6 are rejected under 35 U.S.C. 103(a) over Kim et al.. Claim 6 is also rejected under 35 U.S.C. 103(a) over Kim et al., in view of Kozawa et al. to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

Similarly, claim 21 is rejected under 35 U.S.C. 103(a) over Kim et al.. Claim 21 is also rejected under 35 U.S.C. 103(a) over Kim et al., in view of Kozawa et al. to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

Claim 22. (New) The hollow fiber membrane for blood purification according to claim 2, further comprising: a thickness of a dense layer between 1 and 5 μm.

Claim 23. (New) The hollow fiber membrane for blood purification according to claim 6, further comprising: a thickness of a dense layer between 1 and 5 μm.

Claims 22 and 23 recite the same limitation as claim 7. Claim 22 depends on claim 2 while claim 7 depends on claim 1. Claim 23 depends on claim 6, which depends on claim 1.

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 103(a) over Kim et al.. Claim 6 is also rejected under 35 U.S.C. 103(a) over Kim et al., in view of Kozawa et al. to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

Similarly, claim 22 is rejected under 35 U.S.C. 103(a) over Kim et al..

Similarly, claim 23 is rejected under 35 U.S.C. 103(a) over Kim et al.. Claim 23 is also rejected under 35 U.S.C. 103(a) over Kim et al., in view of Kozawa et al. to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

Claim 24. (New) A blood purification apparatus comprising the hollow fiber membrane according to claim 2, installed in a cylindrical container having two nozzles for flowing a dialysate, the cylindrical container having both ends fabricated with a potting material for separating the hollow inside of the membrane from the outside by a membrane wall and the cylindrical container further having a header cap for flowing blood fitted on both ends.

Claim 25. (New) A blood purification apparatus comprising the hollow fiber membrane according to claim 6, installed in a cylindrical container having two nozzles for flowing a dialysate, the cylindrical container having both ends fabricated with a potting material for separating the hollow inside of the membrane from the outside by a membrane wall and the cylindrical container further having a header cap for flowing blood fitted on both ends.

Claim 26. (New) A blood purification apparatus comprising the hollow fiber membrane according to claim 7, installed in a cylindrical container having two nozzles for flowing a dialysate, the cylindrical container having both ends fabricated with a potting material for separating the hollow inside of the membrane from the outside by a membrane wall and the cylindrical container further having a header cap for flowing blood fitted on both ends.

Claims 24-26 recite the same limitation as claim 8. Claim 8 depends on claim 1. Claims 24-26 depend on claims 2, 6, and 7, respectively.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al., in view of Carlsen et al. for the specifics of the recited blood purification apparatus. Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 103(a) over Kim et al.. Claim 6 is also rejected under 35 U.S.C. 103(a) over Kim et al., in view of Kozawa et al. to teach the overall mass transfer coefficient calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

Similarly, claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al., in view of Carlsen et al. for the specifics of the recited blood purification apparatus.

Similarly, claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al., in view of Carlsen et al. for the specifics of the recited blood purification apparatus. Claim 25 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al., in view of Carlsen et al. for the specifics of the recited blood purification apparatus – in further view of Kozawa et al. to teach the overall mass transfer coefficient

calculation in the context of polysulfone / polyvinylpyrrolidone hollow fibers used for blood purification.

Similarly, claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al., in view of Carlsen et al. for the specifics of the recited blood purification apparatus.

Response to Arguments

30. Applicant's arguments filed June 26, 2009 have been fully considered but they are not persuasive.

31. Applicant makes the following argument.

> "Applicants submit that Kim et al., Kozawa et al., and Carlsen et al. all fail to teach or suggest the presently claimed, including, in particular, a hollow fiber membrane for blood purification obtained by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone, and dimethyl acetamide, through an air gap whose solvent gas concentration is 470 ppm or more and 1,000 or less. There is simply nothing, in any of these documents – alone or in combination – that would teach or suggest this element of Applicants' claimed invention." Applicants Remarks, p. 8, line 34 to p. 9, line 2.

32. The examiner responds as in the above patentability analysis. The claim 1 limitation under discussion is that of running the spinning solution "through an air gap whose solvent gas concentration is 470 ppm or more and 1,000 or less." This limitation was rejected for indefiniteness under 112, paragraph 2 because the Specification does not define what the solvent gas is and does not tie the presence of the solvent gas in the air gap to a patentable difference in the apparatus being claimed.

33. In the patentability analysis above, the examiner interpreted the solvent gas to be water vapor. This interpretation is in line with ¶ 80 of the Specification which discloses a method for

reducing structural shrinkage of the hollow fiber membrane during manufacture by running the coagulation (water) bath temperature between 80^{O}C 100^{O}C below the air gap. Furthermore, Table 1 above shows water vapor concentration in ppm at 70% and 95% relative humidity when temperatures range between 60^{O}C and 95^{O}C and the pressure is atmospheric. As can be seen in Table 1, water vapor (solvent gas) concentration falls within the 470 to 1000 ppm range recited by the indefinite limitation.

34. When the solvent gas is interpreted to be water vapor, the patentability analysis on the merits found that Kim et al. discloses or suggests all limitations recited in claim 1, including the limitation that applicant is arguing – namely that of running the spinning solution "through an air gap whose solvent gas concentration is 470 ppm or more and 1,000 or less." The relevant part of the analysis is repeated below.

35. Kim et al. discloses the claimed invention except for the humidity in the air gap being saturated, instead of the recited 70% to 95%. Both Kim et al. (¶ 195, lines 9-13) and applicant run the hollow fiber from the spinneret through an air gap and then promptly introduce the hollow fiber into a water bath. In applicant's words the water bath is described as "a coagulation bath containing water as a main component installed below the spinneret." Specification, ¶ 76, lines 12-14. Given both processes use water baths, it would have been obvious to one of ordinary skill in the art to make the Kim et al. hollow fiber with 95% humidity in the air gap instead of 100% humidity since this is the simple substitution of one known element (100 % humidity) for another (95% humidity) to obtain predictable results (the hollow fiber is plunged into a water bath with high humidity at the water bath's interface and the hollow fiber is cooled through the water bath and wound around a bobbin).

36. Regarding the "solvent gas" limitation, this was discussed above in the 112 rejection. As stated there, Kim et al. discloses a solvent gas of water vapor in the air gap which meets the recited limitation of "an air gap whose solvent gas concentration is 470 ppm or more and 1,000 or less and whose relative humidity is 70% to 95%."

37. Applicant makes a second argument.

> "In order to set the albumin sieving coefficient at 0.6% or less, Applicants realized that the structural change before and after drying of the hollow fiber membrane . . . must be kept to a minimum. Applicants have also discovered that the structure formation is greatly affected not only by temperature and humidity, but also by the solvent gas concentration in the air gap . . . Applicants respectfully submit that Kim et al., Kozawa et al., and Carlsen et al., all fail to recognize what Applicants have discovered, which is the importance of minimizing structural change before and after drying, and thus, fail to suggest any modifications that would lead to the presently claimed invention." Applicant's Remarks, p. 8, lines 31-34.

38. As noted in the response to the first argument, applicant's process in the air gap is the same process that Kim et al. runs. Both Kim et al. (¶ 195, lines 9-13) and applicant run the hollow fiber from the spinneret through an air gap and then promptly introduce the hollow fiber into a water bath. In applicant's words the water bath is described as "a coagulation bath containing water as a main component installed below the spinneret." Specification, ¶ 76, lines 12-14. Both processes run the water bath at similar temperatures. Kim et al. runs it 55^{O}C and then washes the wound fiber with hot water at 90^{O}C for 90 minutes. Kim et al., ¶ 195, lines 9-15 and ¶ 188, lines 14-20. Applicant runs the water bath at 80^{O}C to 90^{O}C with no hot water wash following. Specification, ¶ 80, lines 1-4. Both applicant and Kim et al. achieve albumin sieving coefficients of 0.6% or less as recited. Specification, ¶ 23. Kim et al., Table 1, Comparative Example 1 and Example 1, using calf serum as stated in ¶ 169 – where the two Kim et al.

examples teach an albumin sieving coefficient of 0.4% to 1.1% as the polyvinyl pyrrolidone content in the spinning solution ranges from 0 to 7 parts, respectively.

39. In summary, Kim et al. discloses the claimed invention, including the recited albumin sieving coefficient at issue. The similar albumin sieving coefficient is to be expected since both applicant's post-spinning process and Kim et al.'s post-spinning process are run in a similar manner and in hot water temperatures up to 90^{O}C.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

41. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise R. Anderson whose telephone number is (571)270-3166. The examiner can normally be reached on Monday through Thursday, from 8:00 am to 6:00 pm.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter D. Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DRA/

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797